IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION, | ) | |
| Plaintiffs, | ) | C. A. No. 98-80 (SLR) (Consolidated with C. A. No. 98-314 (SLR) and C. A. No. 98-316 (SLR)) |
| v. | ) | |
| MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., | ) | |
| Defendants. | ) | |

**MEDTRONIC'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER OF LAW**

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INTRODUCTION

The Court should grant judgment as a matter of law that Medtronic's stents do not infringe because those stents are fundamentally different from the invention of the Lau patents.

The Lau specification is clear. What Lau purported to invent was "a series of radially expandable cylindrical elements *which are spaced longitudinally close enough* so that small dissections in the body lumen may be pressed back into position against the lumenal wall, *but not so close* as to compromise the longitudinal flexibilities of the stent." (AX1 at col. 2:1-6). (Emphasis in the quoted material is added unless otherwise noted). ACS reiterated this basic requirement in the specification and figures of the Lau patents, and in its statements to the Patent Office during prosecution. The intrinsic record teaches that *this spacing is not only necessary but also inherent* in the structure of the cylindrical elements themselves, which ACS defined as being comprised of a plurality of U-, W- and Y-shaped members.

In contrast to Lau's invention, it is undisputed that Medtronic *specifically* designed its stents to *avoid* spacing between the rings to prevent them from failing. That is because Medtronic's stents *transfer* the bending loads at the welds and bend only within, not between the rings. There is nothing extending between the rings of Medtronic's stents, which are fused together with no material added. Thus, Medtronic's stents achieve flexibility in a fundamentally different way from Lau's invention. ACS's expert, Dr. Segal, conceded that if there is nothing extending between the rings, then there can be no Y-shaped members. There also are no "connecting members" that "extend between" adjacent rings.

ACS also failed to prove that any Medtronic stent (with the exception of the MicroDriver and Driver) satisfies the length-less-than-diameter ("L<D") requirement *at the same time* that it satisfies other limitations in the asserted claims. To prove that Medtronic's stents satisfied the "longitudinally flexible" and "radially expandable" limitations, ACS presented evidence of the stents in the crimped state. But when it came to the L<D limitation, ACS had to rely on the expanded state where the diameters are greater. ACS presented no evidence that Medtronic's stents are flexible or expandable in that state.

ACS also failed to prove two other fundamental elements of its case – that the accused products infringed the patents during the term of the patents and that the Lau patents were properly assigned to ACS. First, the unrebutted evidence showed that certain products *were not made or sold at all* during the terms of certain patents, and thus could not possibly infringe them. It thus is not a question of "when each stent was discontinued after it began infringing," as ACS asserts. Second, ACS simply did not put on any evidence of ownership in the trial record notwithstanding being on notice of its deficiency.

Finally, JMOL should be granted that the Lau patents are obvious. It was undisputed that there was a clear motivation in the art in 1991 to design strong, yet flexible stents, and that it was understood that one way to achieve this was to make stents shorter. It also was understood that shorter stents could be connected together to prevent them from migrating. The main dispute at trial was over whether there was some limit on what skilled artisans considered too short (and ACS offered no evidence of this) and whether the disclosure of a 1 mm stent in the Boneau '331 patent should be given credence. Because ACS offers no authority for its position that the jury was free to disregard this explicit teaching of the Boneau patent, the Lau patents should have been found invalid for obviousness.

## ARGUMENT

### I. MEDTRONIC'S STENTS DO NOT INFRINGE BECAUSE THEY DO NOT HAVE AN UNDULATING PATTERN COMPRISED OF A COMBINATION OF U-, W- AND Y-SHAPED MEMBERS

#### A. Under The Federal Circuit's Recent *Phillips* Decision, Claims Must Be Interpreted In Light Of The Invention As A Whole As Described In The Specification And Prosecution History.

In ultimately construing "undulating pattern" during trial, the Court commented on the closeness of the issue and the difficulty the Court had in reconciling the claim language of the Lau patents with the statements in the specification and prosecution history. (Tr. at 1711:8-22). The Court stated that it "felt it was more important … under the latest iteration of what the Federal Circuit looks at to make the claim language consistent rather than trying to make the specification, [and] prosecution history consistent with the claim language." (*Id.* *See also* D.I. 615). ACS also urged the Court in its answering brief that it was

proper to look to the specification only where there "are words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." (*See, e.g.*, D.I. 673 at 12, 14, citing *Interactive Gift Express, Inc. v. CompuServe, Inc*., 256 F.3d 1323, 1331 (Fed. Cir. 2001), and *Teleflex, Inc. v. Ficosa N. Am. Corp*., 299 F.3d 1313 (Fed. Cir. 2002)).

The Federal Circuit's *en banc* ruling last week in *Phillips v. AWH Corp*., 03-1269 (Fed. Cir. July 12, 2005), has now resolved that conflict and held that the claims should not be construed in isolation. Rather, the Federal Circuit held that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." (Slip op. at 10). Confirming its holdings in *Markman* and *Vitronics,* the Court emphasized that the specification (unlike dictionary definitions) "usually *is dispositive*; it is the *single best guide* to the meaning of a disputed term." (*Id*. at 13 (citations omitted)). Thus, the Federal Circuit held that "it is therefore entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." (*Id*. at 16). The same is also true for the prosecution history. (*Id.* at 17). ("Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.").

*Phillips* unambiguously rejected the approach advocated by ACS and the cases it cites suggesting that the specification should only be consulted for statements of "clear disavowal," or as a check on dictionary meaning. (*Id.* at 23-24). The Federal Circuit held that such an approach improperly restricts the role of the intrinsic record in claim construction and improperly "focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." (*Id*. at 24-25). The Court also noted that "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words." (*Id.* at 25). The Court explained that these differing objectives counsel against relying on dictionary definitions, which can lead to claims of overbroad scope if divorced from the patent:

> The problem is that if the district court starts with the broad dictionary definition in every case and fails to fully appreciate how the specification implicitly limits that definition, *the error will systematically cause the construction of the claim to be unduly expansive. The risk of systematic overbreadth is greatly reduced if the court instead focuses at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down.*
>
> * * * *[T]hus, the use of the dictionary may extend patent protection beyond what should properly be afforded by the inventor's patent*.

(*Id.* at 26). Thus, it would be improper to rely upon a general dictionary definition of "undulating," divorced from context, which is inconsistent with ACS's own explicit and implicit teachings.

### B. The Descriptions In The Specification Require *Spaced Apart* Cylindrical Elements, Impossible Without Either W- Or Y-Shaped Members (Or Both).

As the Federal Circuit ruled in *Phillips*, claim construction is not an abstract exercise by which definitions are pulled from the air, but must be viewed in terms of how the applicant described its invention. In light of this guidance, the Court's initial inclination in construing "undulating" was plainly correct: the cylindrical elements of the Lau patents must consist of a plurality of U-, W-, and Y-shaped members. (D.I. 579). Medtronic set forth in detail in its opening brief how ACS defined its invention and will not repeat those arguments here. (*See* D.I. 654 at 4-15). Instead, Medtronic will limit itself to addressing ACS's arguments.

The main thrust of ACS's response is to repeat its argument that its own words should not be taken at face value. For each of the many times ACS affirmed that the serpentine structure of the cylindrical elements must be comprised of a plurality of these letter-shaped members, ACS has a reason why the intrinsic evidence does not mean what it says. ACS argues, for example, that the inventors described "serpentine" (which they explicitly defined as incorporating U-, Y- and W-shaped members) as "merely an *example* of 'undulating'" (D.I. 673 at 13), and that the discussion of the U's, W's and the Y's "was confined entirely to the projecting edges feature," which is not found in all claims. (*Id.* at 15-16). Finally, ACS argues that U's, W's and Y's do not define "undulating" because "only three dependent claims mention U's, W's and Y's." (D.I. 673 at 15).

All this not only ignores the fact that the specification offers absolutely no other definition of serpentine or undulating pattern; it also ignores that, as the Court held:

> [D]uring the prosecution of the patent, the patentee continuously refers to these shaped structures in describing his invention and distinguishing it from others. Therefore, based on the prosecution history it is evident that, despite the references to the preferred embodiment in the written description, the patentee thought that cylindrical elements were defined by these shaped structures.

(D.I. 542 at 3, n.5). Clearly, ACS's statements about the letter-shaped structures of the cylindrical elements, while sometimes made in particular contexts, were nonetheless definitional. *See Alloc, Inc. v. International Trade Com'n*, 342 F.3d 1361, 1368-70 (Fed. Cir. 2003) (where specification shows that invention was exclusively directed towards flooring products with "play" in them, "play" was imported into claims); *CR Bard, Inc. v. United States Surgical Corp.*, 388 F.3d 858, 865 (Fed. Cir. 2004) (construing "plug" to require a pleated surface where there were "statements of general applicability" defining the plug as having a pleated surface and where the preferred embodiments describing the surface of the plug universally described a pleated plug); *Bell Atl. Network Servs. Inc. v. Covad Communs. Group, Inc.*, 262 F.3d 1258, 1273 (Fed. Cir. 2001) (limiting "mode" to three possible modes described in the specification because "the patentees defined the term 'mode' by implication . . . [T]he three modes described in the Detailed Description of the Preferred Embodiments describe the three possible modes of the invention, and the claims are not entitled to any broader scope."). ACS offered no other definition of serpentine, and certainly none consistent with the need to space elements apart, as the specification requires.

Moreover, the passage where ACS defined the serpentine pattern do not limit its description to explaining how projecting edges work, as ACS now contends (*see* AX1 at 6:8-16):

> *In keeping with the invention*, and with reference to FIGS. **4** and **12-14**, cylindrical elements **12** *are in the form of a serpentine pattern **30***. As previously mentioned, each cylindrical element **12** is connected by interconnecting elements **13**. Serpentine pattern **30** is made up of a plurality of U-shaped members **31,** W-shaped members **32**, and Y-shaped members **33**, each having a different radius so that expansion forces are more evenly distributed over the various members.

In describing the projecting edge feature, ACS turned to the *general structure* of the cylindrical elements

to explain how the edges are formed. (*Id.* at 2:47-52). At no point did ACS suggest that the structure of the cylindrical elements was somehow different for stents claiming this feature.

Nor does ACS's attempt to parse the introductory phrase "in keeping with the invention" bolster its case. It is true that "in keeping with" *could* be used in a way that does not define, as in ACS's proffered example, "In keeping with the business attire dress code, he wore a dark suit and red tie." (D.I. 673 at 14, n.5). But a plain reading of the specification makes clear that this is not the sense in which it is used in the Lau patents: "*In keeping with the invention*, and with reference to FIGS. 4 and 12-14, cylindrical elements *are* in the form of a serpentine pattern 30." (AX1, 6:7-10).

The fact that certain specific combinations of U's, Y's and W's are mentioned in certain dependent claims is also unpersuasive. (D.I. 673 at 15). As Medtronic noted in its opening brief, these dependent claims describe particular embodiments which have a *particular arrangement and placement* of letter shaped members (D.I. 654 at 11).[1] Indeed, by explicitly defining an undulating pattern (and, hence, a cylindrical element) in terms of U's, Y's and W's, Lau saved the trouble of having to repeat that and other attributes of his stent invention specifically in every claim.

ACS took the same approach with its L<D requirement. As with the U's, Y's and W's, some claims, but by no means all, specifically refer to the requirement.[2] ACS nonetheless urged the Court to graft the L<D limitation into the definition of cylindrical element in all asserted claims (*see* D.I. 419 and 467), even though it renders other limitations in some claims surplusage.

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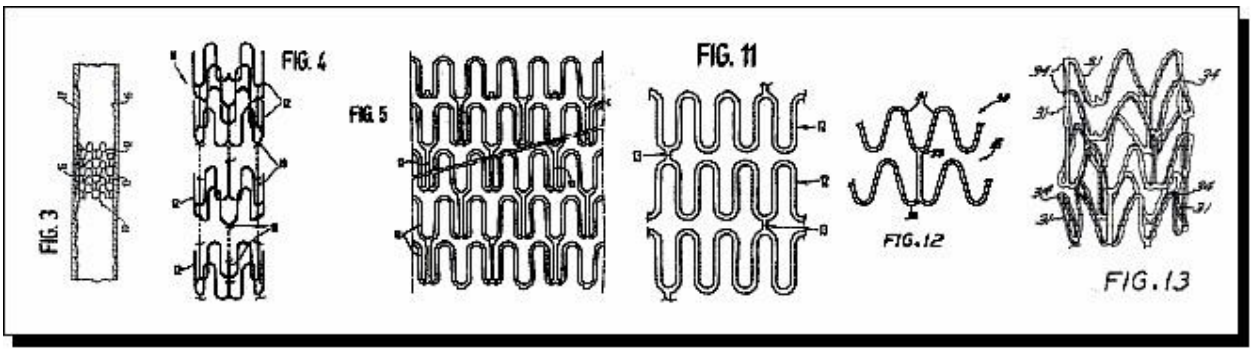
[1] For example, claim 4 claims an embodiment where *the peaks and valleys* have a serpentine pattern. (The specification teaches that various configurations for the placement of interconnecting elements are possible, such as along the sides of the undulations, but that placement at the peaks or valleys of the undulating structural elements is preferred. (*See* AX1 at 2:67-3:3; 5:45-51; 6:4-8).) Similarly, claim 5 and the claims depending from it claim an embodiment consisting of a plurality of U-shaped *and* a plurality of Y-shaped *and* a plurality of W-shaped members (i.e., a combination of all three members). These claims are different from and narrower than a claim to just an "undulating pattern," which, under Medtronic's definition, need have only two of the three letter shapes.

[2] For example, '168 patent, claim 18 reads: "The stent of claim 12, wherein each cylindrical element has a length and a diameter, the length of each cylindrical element being less than the diameter of each cylindrical element."

ACS also argues that, notwithstanding its express statement in the specification that the elements "*are* spaced longitudinally close enough … *but not so close*" (AX1 at 2:1-6), the patent should not be read to call for an "arbitrary amount of spacing between cylindrical elements." (D.I. 673 at 14). There is nothing "arbitrary," however, about requiring *some* spacing. Nor does the specification in any way suggest, as ACS argues, that the spacing is optional so long as the stent is flexible. Indeed, by explicitly recognizing the need for *some* spacing, ACS "manifestly excluded" structures that have *no* spacing.

### C. Consistent With *Phillips*, The Figures Of The Lau Patents And The Prosecution History Confirm Medtronic's Proposed Construction.

Each of the figures in the Lau patents unambiguously depicts some combination of U's, W's and Y's. This sampling (with Y's 33, W's 32, and connectors 13) is not only representative. It is exclusive -- no other designs are disclosed or depicted:




Moreover, the dialogue reflected in the prosecution history confirms the appropriateness of Medtronic's proposed construction. On this point, ACS now argues that it and the Examiner agreed that undulating patterns are *always* made up of *only* U-shaped members and that the Y's and W's are just U's plus connecting elements. (D.I. 673 at 16). In other words, ACS argues that the "undulating pattern" of the Lau patents is *only* U-shaped members, and to the extent there is any other structure associated with the elements, it is all connector.

This position, however, is impossible to square with the figures from the patent, in which absolutely *every* undulating pattern depicted is made up of more than just U's. Moreover, if, as ACS now

seems to contend, the Examiner had originally thought that the Y- and W-shaped members were a composite of two different structures – the "normal" serpentine pattern of U's and a connecting element (the tail of the Y or middle of the W) – then there would have been no reason for confusion on his part. He would have assumed the only thing that distinguished a Y or a W was the addition of a connector to a U, and he would never have raised a concern. What caused the Examiner's confusion was his understanding that the "Y-shaped and W-shaped members are nothing more than part of the normal serpentine pattern …." He could not understand "what applicants consider the connecting elements if the cylindrical elements included such [letter-shaped] members." (AX11 at 44-45).

This is not a case where the prosecution history represents a "negotiation" between the Examiner and the applicant, let alone a disagreement. As noted in Medtronic's brief, ACS never disagreed with the Examiner's understanding that the *cylindrical elements* included such letter-shaped elements. Instead, ACS amended the claim to identify *a portion of the Y-shaped member* as the connecting element based on their common understanding that such portion was also part of the undulating pattern. (D.I. 654 at 10). Both the Examiner and the applicant obviously understood that the cylindrical elements need to have either Y-shaped members or W-shaped members, or both, and they further understood the separateness of the cylindrical elements and connecting elements.

ACS points to its statement that "the tail portion of the Y-shaped member is the connecting element between the cylindrical elements" to argue that it purportedly made clear that "the connector portion of a W- or Y-shaped member is *not* part of the 'cylindrical elements' recited in the claim." (D.I. 673 at 16-17). ACS said no such thing, however. Indeed, ACS did not even mention the *W-shaped members* in its response; nor did it take exception to the Examiner's understanding that the *Y- and W-*shaped members are part of the serpentine pattern. The fact that ACS said that the connecting member of claim 5 is a portion of the *Y-shaped* member does not mean that the tail of the Y will always be a connecting member. A number of figures of the patents give examples of Y- and W-shaped members with extensions that do not extend between cylindrical elements and are not connected to anything else,

and thus are not connecting members. (*See, e.g.*, AX1 at Figs. 3, 4, 5, 11 and 13).[3]

D. The Court Should Reject ACS's "Plain Meaning" Argument.

Notwithstanding its statements in the intrinsic record, ACS urges the Court to consider the meaning of the term "undulating" in a vacuum. Seeking to broaden the scope of its claims beyond what it actually invented and claimed, ACS identifies what it contends is the generally accepted, all-purpose definition of "undulating," and defies Medtronic to come up with "evidence of manifest exclusion or restriction [that] represents a clear disavowal of claim scope." That language is out of the *Teleflex* and *Texas Digital* cases; and that approach was specifically rejected by the Federal Circuit in *Phillips*. (Slip op. at 23-24). As the *Phillips* court explained, ACS's blind resort to dictionary definitions, untethered to the specification, would result in patent protection beyond what can be properly afforded by the patent. (*See* Slip op. at 26).

But ACS's position is problematic for other reasons. ACS does not point to any piece of evidence that the word "undulating pattern" had an ordinary meaning *in the stent art* at the relevant time. It offers no dictionary of medical terms that use the phrase, nor points to any usage in the contemporary stent literature. Nor did ACS's witnesses, Dr. Segal or Dr. Kahn, testify that "undulating" had an ordinary or customary meaning *in the stent art* in the early 1990s.

ACS asserts that Medtronic does not dispute ACS's chosen "ordinary meaning," and quotes Medtronic's expert, Dr. Vito. (D.I. 673 at 12). ACS takes Dr. Vito's testimony out of context, however. Dr. Vito actually testified that undulating pattern was an ill-defined term in the technical stent art (*Id.* at 1075:18-1076:9):

> Q. Sir, would you agree with me that ACS's proposal is closest between the two parties' proposals, that ACS's is closest to the ordinary meaning of undulating patented?

---

[3] As the foregoing makes clear, construing "cylindrical element" to include Y- and W-shaped members does not make the separate limitation of "connecting elements" surplusage, as the two limitations are not synonymous. There will be some W and Y shaped members with no connecting elements. There also can be cylindrical elements with discrete connecting elements that extend between their Y-and W-shaped members.

A. Well, I can't answer that. I just don't know. To me or to who? *I think undulating is a pretty ill-defined word.*

Q. Sir, things that are considered undulating, do they often have Y-shaped members? An undulating road, would that be something thought of to have –

A. You can make an argument that way. My sense is, well, what is Mr. Lau teaching in the patent and so I went to the patent to see what he meant.

Q. Sir, I'm not asking you --

A. It doesn't matter what I think an undulating pattern is. It matters what Mr. Lau thinks it is.

The passage of Dr. Vito's testimony that ACS quotes related to the definition of "undulating" in the abstract, not in connection with how those of ordinary skill would have used the term at the relevant time or in connection with how the patent used it. Moreover, the general dictionary to which ACS referred during Markman was "not . . . written by or for skilled artisans and therefore [does] not reflect the understanding of a skilled artisan in the field of the patent." *Phillips,* slip op. at 20. Thus, ACS's attempt to relying on dictionaries of general application simply fails.

### E. Medtronic's Stents Do Not Infringe Because They Do Not Have A Plurality Of Y-, W-, And U-Shaped Members.

As Medtronic noted in its opening brief, Dr. Segal, ACS's expert, admitted that "if there's nothing extending between the two rings, you couldn't have a Y." (Tr. at 6:23-27). He also admitted that there is no material added between the cylindrical rings of Medtronic's stents when they are welded by autogenous fusion. (*Id.* at 596). In light of these admissions, Medtronic's stents clearly lack the required combination of W-shaped, U-shaped and Y-shaped members.

In its answering brief, ACS tries to piggyback on the jury verdict of infringement of the '154 patent, arguing that the jury necessarily found that Medtronic's stents have Y-shaped members because of the implicit finding that Medtronic's autogenous welds "extend between" adjacent cylindrical elements. (D.I. 673 at 18). Even assuming that the jury verdict on the '154 patent were to stand (which for all the reasons discussed in the following section, it should not), a finding that Medtronic's stents have "connecting elements," does not necessarily mean that the jury also found a plurality of W-, Y- and U-

shaped members. As explained above, the W- and Y-shaped members of the cylindrical elements, and connecting elements of the Lau patents, are not synonymous. Moreover, the jury may well have been misled by ACS's arguments that the connecting element need not be a discrete structure or have length to extend between cylindrical elements. As ACS notes, there was no express "spaced apart" requirement for "connecting members." In contrast, there can be no question that for there to be a Y- or W-member, *there must be some discrete, identifiable structure*, however small, *situated between* the rings to form the tail of a Y or the middle of a W. Medtronic's stents indisputably lack such a discrete, identifiable structure, separate from the rings themselves.

## II. BECAUSE MEDTRONIC'S PRODUCTS DO NOT HAVE STRUCTURES WITH A ***LENGTH*** THAT ***EXTENDS BETWEEN*** CYLINDRICAL ELEMENTS, THEY LACK "CONNECTING ELEMENTS."

Medtronic stents (with the exception of the BeStent2) are made up of sinusoidal rings that are formed individually and then welded together by an autogenous weld process. It is undisputed that this process involves abutting two crowns together, applying pressure to eliminate any space between them, and heating them with a laser until they fuse together, all without adding any additional material. (Tr. at 788-791). It is also undisputed that, viewed from the underside by scanning electron microscope such welded crowns are unquestionably in "intimate contact," with no space separating them. (Tr. at 792-94; Exh. DTX-149-A) (attached as Ex. A). The undisputed evidence at trial establishes that, while fused crowns are joined at a weld-affected area, there is no structure that "extends between" them or has a length disposed between the crowns.

ACS cites a purported "concession" by Medtronic's Jeffrey Allen, who supposedly conceded that "a *new* structure – a 'weld' – which is created from metal borrowed from the two adjacent crowns." (D.I. 673 at 19 (citing Tr. at 854)). What Mr. Allen actually said was:

> Q. All right. The crowns come together. The heat is applied. Some of the metal from one crown and some of the metal from the other crown come together, and they form something new, called the weld?
>
> A. *They mix together and form an autogenous fusion weld.*

Q. Which is new, because you didn't have a weld before?

A. *It's new that they're connected now.*

Q. And the weld itself is new because it wasn't there before; correct?

A. The material that -- yes. That's correct.

(Tr. at 854:11-22). Contrary to ACS's suggestion, ACS never actually asked Mr. Allen if the weld constituted a "new structure." Indeed, Mr. Allen made quite clear that there is no new structure and no added length. The only thing that is new is the weld itself which does not extend between the crowns but is part of them. (Tr. at 796:7-17).

ACS next contends that Dr. Vito also "admitted" that the weld is "situated" between the crowns. The record to which ACS cites actually reads as follows:

> Q. And where they're welded together, do the rings of these crowns touch after they're welded?
>
> A. Yes. The way the weld is done -- and Mr. Allen explained it yesterday and maybe I will just reiterate it again -- the individual segments of the stent are put on a tube and brought together and each crown is pressed together with -- it looks like a relatively small force, but it's a very high pressure between the crowns *because they're just essentially joined point to point at this time.* And then they're heated up while you're applying that pressure by a laser.
>
> And when they're heated, they essentially move together slightly and when, of course, the cooling occurs, *they're basically welded together and in intimate contact*.
>
> *So there's really no room between there for anything to come between the crowns other than the weld.*
>
> You know, this is really a very simple welding process. It's technically, as I said before, very difficult to do, but it's really a very simple idea. You just push them together and melt them and then you have one piece.

(Tr. at 971:12-972:8). Thus, Dr. Vito actually testified that there is nothing between the crowns because they are "in intimate contact." Indeed, Dr. Vito further explained that (Tr. 917:18-22):

> So the idea of pressing them together kind of makes sense. I mean, you want to melt them and at the same time push them together so that the contact region between the two is significant and makes for a strong, reliable weld.

Importantly, Dr. Vito plainly testified that there is an area made up of material from the abutted crowns of

Medtronic stents that is affected by and constitutes the weld. (Tr. 971-72). The fact that the *area of the crowns affected by the weld* is required to have minimum length simply has nothing to do with whether there is a connecting member that *extends between* the crowns.

The distinction between these two different senses of the word "between" -- joining and extending between -- is very important given the disclosure of the Lau patents and the context out of which ACS's stent work arose. Indeed, although the evidence is quite clear that Medtronic's products have no "connecting element . . . extending between" the individual rings as described in the Lau patents, this distinction was plainly lost upon the jury.

While ACS admits that it heavily relied at trial on Medtronic's specifications (D.I. 673 at 21-22), it has no answer to the unrefuted evidence that these specifications show only a "weld-affected area," and not any structure of a weld inserted or created between the crowns, and that had there been any such structure, it would have to be described in the specifications. (*See* D.I. 654 at 19). ACS also has no answer to Mr. Allen's testimony that, by design, the welds *cannot extend between* the crowns, but rather must occupy the same space as the crowns, in order to be able to transfer the bending loads. (*Id.* at 17). The only other evidence on which ACS relies – photographs which it took of Medtronic's stents – simply cannot create "connectors" where as a matter of engineering there are none.

## III. ACS DID NOT PROVE THAT MEDTRONIC'S STENTS MEET THE LENGTH-LESS-THAN-DIAMETER LIMITATION AT THE SAME TIME THAT THEY ARE FLEXIBLE AND EXPANDABLE.

This Court construed a "longitudinally flexible stent" to mean "a stent that is flexible along its longitudinal axis (i.e., length) *to facilitate delivery* through tortuous body lumens." (D.I. 542 at 2). It also construed "cylindrical element" in pertinent part to mean "a *radially expandable* segment of a stent having longitudinal length less than its diameter." (*Id.* at 2-3). The only evidence ACS presented at trial concerning the longitudinal flexibility and expandability of Medtronic's stents pertained to their *crimped state*. (D.I. 654 at 20-21 (citing Tr. at 466, 476-77)). Yet because ACS had no evidence that Medtronic's stents (with the exception of the Driver and the MicroDriver) have L<D in the crimped state, ACS turned

its attention to the *expanded state* to prove infringement of that limitation. ACS offered no evidence whatsoever that Medtronic's stents are longitudinally flexible or expandable in the expanded state.

It is, of course, fundamental that all limitations of a claim must be met for there to be infringement. *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998). Yet in its zeal to prove infringement, ACS failed to prove that all limitations are met at the same time in Medtronic's products. Instead, it mixed and matched its proofs, borrowing some elements from stents in one condition and other elements from stents in another condition (like arguing that an ironing board can fairly be described as "a structure measuring 5 feet in both the vertical and horizontal direction" because it is 5 feet "tall" when collapsed and stood on end and it is 5 feet "wide" when set up on its legs). Moreover, while ACS accuses Medtronic of engaging in belated claim construction, it is ACS that does just that by trying to insert a provision that L<D can be met in any state. ACS improperly urged the jury to apply the limitation as if it read not "length *is* less than diameter," but rather "length *can be made* less than diameter through expansion."[4] Indeed, ACS tries again to rely on its rejected *Teleflex* argument that claims must be read broadly to permit L<D to be measured in any state because the specification does not use words of "manifest exclusion or restriction." (D.I. 673 at 27). The *Phillips* decision makes clear that no such wording is required. (Slip op. at 24). And ACS offered no evidence of how the requirement would be understood by one skilled in the art.

ACS also argues that a stent is "expandable" in the "as manufactured" (i.e., uncrimped) condition. While this *may* be true (although ACS presented no evidence of this as to most Medtronic stents), the resulting stent still would not meet the other requirement that the stent be longitudinally flexible to *facilitate delivery*. Nor does ACS's reference to claim 14 of the '154 patent, which claims "radially expandable cylindrical elements in an expanded condition [having] a length less than diameter," help it.

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[4] Notably, ACS knew full well how to draft such a claim when it wanted to. Claim 14 of the '154 patent recites "The stent of claim 12, wherein said radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof." This claim covers a stent made up of elements that both *are* L<D when they are in a longitudinally flexible, expandable state and also *can be made* L<D upon expansion.

Contrary to ACS's assertion, a fair reading of that claim does not require that the cylindrical elements be simultaneously crimped and in an expanded condition. Rather, what that claim requires is that the elements have L<D in both an expanded and crimped position.

ACS also argues that flexibility is not only important in the crimped state. While this may be true, the Court has specifically construed the "longitudinally flexible stent" limitation to require a stent that "facilitates delivery" through tortuous body lumens. There is no evidence in the record that that Medtronic's stents are flexible in any state other than the crimped state.

ACS's assertion that Medtronic is raising this argument for the first time is also flatly wrong. Medtronic's counsel explained at length in closing argument how ACS had failed to prove that the L<D criterion was met. (Tr. at 1811-19) (detailing "three reasons why the only proper time to measure [L<D] is when [the stent is] crimped, not as manufactured, not expanded, but as crimped.").[5] Indeed, Medtronic also raised ACS's failure to prove that the accused stents infringe the L<D limitation in its motions for JMOL both at the close of ACS's case, and its renewed JMOL motion at the close of all evidence. (D.I. 598 at 2 and 2-13; Tr. at 1678).

ACS finally argues that Medtronic is taking a different position than it took when arguing the invalidity of ACS's patents. What ACS ignores is that Medtronic's invalidity case followed ACS's infringement case, during which ACS argued that L<D in the expanded state sufficed for infringement. It is black letter law that "[t]hat which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) (superceded by statute). Medtronic quite properly responded to ACS's infringement proofs by pointing out that, under the same interpretation as ACS proffered, ACS's patents are invalid.

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[5] ACS can hardly claim that it did not know of Medtronic's argument that length less than diameter had to be measured in the crimped state; it attempted to rebut this argument in its own closing, making many of the same arguments that it makes here. (Tr. at 1939-40).

## IV. ACS ALSO FAILED TO PROVE THE REQUIRED ELEMENTS OF OWNERSHIP AND THAT THE ACCUSED PRODUCTS WERE MADE OR SOLD DURING THE TERMS OF THE PATENTS.

### A. ACS Did Not Prove That The Accused Stents Infringed During The Term Of The Patents.

In its opening brief, Medtronic explained that, to prove infringement under Section §271(a), ACS had to show that infringing activity took place "during the term of the patent." (D.I. 654 at 23-24). ACS calls this argument a "red herring," but the fact remains: ACS has not cited a single authority for the proposition that it can split the proof on its cause of action, trying a portion of the elements of infringement to one jury and the remainder to another.

The verdict form asked the jury to determine whether there was "infringement," not whether the products read on the claims. Section 271(a) could not be clearer concerning what is required to prove infringement. And it is simply beyond dispute that ACS offered no evidence for the purpose of establishing that Medtronic made, used, sold or offered to sell its products during the term of any particular patent. ACS certainly made no mention of the issue in its closing argument (even after the deficiency was pointed out in not one, but two motions for JMOL and in Medtronic's proffer (D.I. 636)). And the Court specifically instructed the jury *not* to consider the timing of Medtronic's products in relation to the patents. (Tr. at 1913-1916).

In essence, ACS argues that because each product allegedly infringes some patent, it does not matter that it does not infringe others. Section 271(a), however, requires that infringement be determined patent by patent. Medtronic cannot be held liable for patents it does not infringe. Thus, ACS's assertion that the only issue remaining is "the timing of when each stent was discontinued ***after it began infringing***" is wrong. (D.I. 673 at 2).

ACS cites *AFG Industries* for the proposition that determining infringement is "a two-step process." *AFG Indus. v. Cardinal IG Co.,* 375 F.3d 1367, 1371 (Fed. Cir. 2004). (D.I. 673 at 29, n.11). ACS's remarkable contention appears to be that since the Court construed the claims and the jury compared the claims to the accused products, infringement has been "determined." It hardly bears noting

that neither *AFG Industries*, nor any other case known to Medtronic or cited by ACS, stands for the proposition that the jury in this case (or this Court, for that matter) can dispense with the elements set forth in Section 271(a) on its way to a finding of *infringement liability*. *AFG Industries*, of course, does not address this issue at all.

ACS's analysis of Medtronic's Seventh Amendment argument, is internally inconsistent. Having just argued that the jury was presented with evidence concerning when Medtronic's products were on sale, ACS now avers that the jury was not asked to (and, presumably, did not) consider any of that evidence. ACS is correct that *In re Paoli R.R. Yard PCB Litig.*, 113 F.3d 444 (3d Cir. 1977), the Third Circuit held that discrete issues can be tried to separate juries under appropriate circumstances, but those principles do not apply here. ACS sought and received a separate trial on liability, but failed to offer the proper proof on that question. Now ACS asks the Court to let it make up the gap with the next jury. This is the sort of double dipping of which *In re Paoli* and like cases disapprove.

Finally, ACS cannot shift the burden of proving *non-infringement* onto Medtronic. (D.I. 673 at 31). Nor can it rely on the parties' stipulation that the parties need not present evidence relating "solely" to damages because proof of infringing activity *during the term of the asserted patents*, of course, does *not* relate "solely" to damages: by definition, such evidence relates to liability, too.

B. ACS Did Not Prove Ownership.

ACS likewise cannot deny that, despite being on notice of its failure to prove ownership, ACS never sought to correct its deficiency before the trial record was closed and the case was submitted to the jury. And while ACS now claims that the face of the '154 patent provides *prima facie* evidence of ownership, it cites no legal authority for this proposition.

ACS completely misapplies the *University of New Mexico* case. There, a litigant attempted to defeat a legal claim of ownership by pointing out that MPEP procedures for recording assignments had not been followed. *Univ. of New Mexico v. Scallen*, 321 F.3d 1111, 1121 (Fed. Cir. 2003). Medtronic, however, relies upon the MPEP for an entirely different proposition, as persuasive authority illustrating

that a new assignment is required for the new matter that is, by definition, associated with a continuation-in-part application.

## V. ACS PRESENTED INSUFFICIENT EVIDENCE TO REBUT MEDTRONIC'S CLEAR AND CONVINCING SHOWING OF OBVIOUSNESS.

ACS's brief reveals that much of the key evidence underlying Medtronic's obviousness case is simply not in dispute.

ACS does not dispute, for example, that stent designers before 1991 were looking to achieve strong but flexible stents. Indeed, that was the lynchpin of ACS's own trial presentation. ACS also does not dispute that stents were being made smaller and smaller to improve flexibility and deliverability. That is why Dr. Schatz specifically asked the J&J engineers to give him shorter Palmaz stents to connect together. (Tr. at 1576). Nor does ACS dispute that there was a clear trend (and motivation) in the art to connect multiple small stents to prevent migration, as Dr. Schatz, Dr. Gianturco, and others had done. (Tr. at 1607-1608).

The limitation in art did not come from any lack of desire to make stents shorter or subdivide them. Indeed, Dr. Schatz testified that he told the J&J engineers that he wanted stents as short as they could make them. (Tr. at 1576). The limitation came from the geometry of the Palmaz stent, which simply could not be made any shorter. (Tr. at 1576-1577). Dr. Schatz was told that a shorter Palmaz stent could not be expanded to the desired diameter. (*Id.*). There is no dispute, however, that the Boneau stent does not have this limitation in its geometry and can be made much smaller, including to lengths of 1 mm. Dr. Segal admitted as much. (Tr. 1643).

ACS asserts two arguments in response. First, it argues again that skilled artisans were working on "stents" not "elements." (D.I. 673 at 34). But there is no dispute that stent designers wanted to go smaller. The limitation was the geometry of the existing art (Palmaz), not that stent designers did not want to use something that standing alone would not function as a stent. The Boneau patent solved this problem. Call it a stent, an element, or a "thing" (as Dr. Segal did), Boneau discloses a structure that can

be made in very small lengths and still expand to the desired diameter.

Second, ACS persists in claiming that the Boneau '331 patent does not disclose a 1 mm stent, notwithstanding its explicit teaching that "corresponding ***stents*** may range from one millimeter to two centimeters in length." (*See* D.I. 673 at 35 (quoting Dr. Segal as saying "I don't see any 1-millimeter stents actually disclosed in this patent.")). Interestingly, ACS does not dispute that the 1 mm length of its cylindrical elements correspond ***exactly*** to the length described in the Boneau patents. ACS merely contends that one of ordinary skill in the art reading the words "stents may range from one millimeter stent" would have concluded that a 1 mm stent would not function as a stand alone stent, and thus, would have ignored Boneau's teachings and not done exactly what Lau had done in taking the teachings of Boneau and combining it with other known art. ACS offers absolutely no authority for its position that the jury was free to disregard this explicit teaching because ACS does not believe it.

ACS also points in its brief to what it characterizes as evidence of secondary considerations of nonobviousness: long-felt need (*see* D.I. 673 at 37-38), commercial success (*Id.* at 38), praise in the industry (*Id.*), and failed attempts by others to solve the same problem (*Id.* at 39). This evidence, ACS contended at trial and in its Opposition, raised the "simple question" that Medtronic was "never able to answer . . . for the jury. Namely, if ACS's connected-ring design were so obvious in 1991, why didn't anyone else do it?" (*Id.* at 37).

The answer, of course, that Medtronic could not tell the jury was that the reason ACS experienced its success was because only ACS actually had access to the Boneau sinusoidal ring. (Medtronic's predecessor, AVE, only had access to that technology in 1993, four years after ACS). This highlights the legal and factual fallacy underlying ACS's purported secondary considerations. ACS invited the jury to compare the state of the stent art ***in the real*** world ***before Boneau was known*** with the success achieved by ACS having in fact known about Boneau. As argued more extensively in Medtronic's new trial briefs, the fact that Medtronic was precluded from rebutting ACS's one-sided story and answering the question ACS posed injected the entire invalidity case with error, warranting a new trial.

Even given the state of the record, such as it was, however, ACS's secondary considerations

evidence cannot rebut a clear case of obviousness. *See, e.g., Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768-69 (Fed. Cir. 1988) (affirming grant of JNOV of obviousness, notwithstanding a strong showing of secondary considerations, because "although those [secondary] factors must be considered, they do not control the obviousness conclusion."); *see also EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) (finding obviousness, notwithstanding showing that the invention had become "very successful" in the industry, because the court "remain[ed] convinced that it presents a clear and very strong case of obviousness."). *See also Richardson-Vicks, Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997).

Moreover, this Court has already recognized that secondary considerations such as long felt need carry little weight when the primary 103 reference had been invented not long after the particular need addressed by the patent in suit had first been recognized. *See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 1994 U.S. Dist. LEXIS 21537 (D. Del. Nov. 10, 1994), *aff'd*, 72 F.3d 1577 (Fed. Cir. 1996). *Cf. In re Mahurkar Patent Litig.*, 831 F. Supp. 1354, 1377-78 (N.D. Ill. 1993) (Easterbrook, J.) (discussing persuasiveness of evidence of "*enduring*, unmet need" with "people . . . clamoring for a solution . . . for years"), *aff'd*, 71 F.3d 1573 (Fed. Cir. 1995). Analogously here, the '337 Palmaz patent issued in November of 1988. (AX-1035). Mr. Boneau had conceived his invention and was already testing prototypes of 3.5 to 4.5 mm in the 1988/1989 time frame (Tr. at 1213:13-15), with the resulting Boneau '331 patent formally becoming 103 prior art upon its filing August 24, 1989.

## CONCLUSION

For the foregoing reasons, Medtronic's motion for judgment as a matter of law should be granted.

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